NDA 20-890/S-002

Schering-Plough Consumer Healthcare
Attention: Mr. Alan Mart
Associate Director, Regulatory Affairs
3 Oak Way
Berkeley Heights, New Jersey
07922

Dear Mr. Mart:

Please refer to your supplemental new drug application dated May 29,1998, received June 1, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotrimin AF Solution

This "Changes Being Effected" supplemental new drug application provides for labeling changes based on new warning statements to avoid contact with the eyes.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon final printed labeling enclosed. Accordingly, the supplemental application is approved effective on the date of this letter. .

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Daniel P. Keravich, M.S., M.B.A., Regulatory Health Project Manager, at 301-827-2248.

Sincerely,

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of Over-The-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research